

REMARKS/ARGUMENTS

This Amendment and Response is responsive to the final Office action dated November 18, 2009, setting forth a shortened three-month statutory period for reply. A petition and fee for a five-month extension of time to reply accompany this Amendment and Response.

Claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-51 are pending in the application. Claims 14 and 22 are independent claims. By this Amendment and Response, claims 14, 18, 22, 33-34, 36, and 45-46 are amended, claims 52-55 are new, and no claims are cancelled. Accordingly, after entry of this Amendment and Response, claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-55 are pending, with claims 14 and 22 being independent claims.

No new matter has been added. Support for amendments to independent claims 14 and 22, and dependent claims 15, 18-20, 23, 32-34, 36-43, and 45-55 may be found throughout the specification, for example at paragraphs [0017]-[0018], and the claims as filed.

Applicants have not publicly dedicated, or abandoned, any unclaimed subject matter. Further, the Applicants have not acquiesced to any rejections made by the Examiner in the Office action, but have merely amended claims in an effort to expedite prosecution. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

Claim Rejections Under 35 U.S.C. § 103

Claims 14, 15, 18, 22, 23, 32-34, 36, 42, 43, 45 and 46 are rejected under 35 U.S.C. § 103(a) as unpatentable over EP0888774 to Soft Gel (herein after "EP0888774") in view of US 2003/0232095 to Garti et al. (herein after "Garti"), US 2004/0047922 to Elstner (herein after "Elstner"), and RITO Partnership document ("RITO"). For at least the following reasons, the Applicant respectfully disagrees with these rejections.

Applicants continue to argue that the cited references do not teach "coenzyme Q-10 solubilized in limonene to form a solution . . . with the proviso that the coenzyme Q-10 solubilized in limonene is not in an emulsion, suspension, or elixir."

In an attempt to expedite prosecution of the pending claims, and without agreeing with, or acquiescing to, the Office's rejections, independent claims 14 and 22 are currently amended. Amended claims 14 and 22 now recite numerical ranges of coenzyme Q10 solutions, namely "wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight."

1. The cited art does not disclose the presently claimed solution of coenzyme Q10 in limonene at “about 15 percent up to about 60 percent coenzyme Q-10 by weight.”

According to the M.P.E.P., numerical ranges may be *prima facie* obvious where: (1) the claimed ranges “overlap or lie inside ranges disclosed by the prior art,” *In re Wertheim*, 541 F.2d 257 (CCPA 1976), (2) a reference “discloses a range encompassing a somewhat narrower claimed range,” *In re Peterson*, 315 F.3d 1325 (Fed.Cir. 2003), or (3) a range is “disclosed in multiple prior art references instead of in a single prior art reference,” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317 (Fed.Cir. 2004). § 2144.05(I).

The Office has rejected dependent claims reciting percentages of coenzyme Q10 in limonene. *Office Action*, p. 4. However, the Office concedes that “Garti et al. do not disclose the solubility limit of CoQ10 in d-limonene,” and that Garti only discloses a composition wherein “the oil phase contains 2.45% co Q10 and 17.22% d-limonene, as percentages of the whole.” *Office Action*, p. 4. Thus, Garti’s most concentrated coenzyme Q10 emulsion is only 2.45%. *Garti*, Example C:1 Micellar concentrate, para. [0040].

Garti is explicit in directing those of skill in the art away from the present claims. The 2.45% coenzyme Q10 composition, which is achieved only through use of the multi-component emulsion, is far better than what could be expected with limonene alone: “[t]he capability of . . . nano-sized self-assembled structured concentrates to solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant.” *Garti*, para [0029]. Not only is there no overlap of ranges, but Garti teaches that the highest percent coenzyme Q10 that maybe achieved by a single solubilizing compound is several fold lower than 2.45%.

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. While Elstner claims a preparation “contain[ing] a terpinene-containing etherial oil or terpinene,” and coenzyme Q (Q10), there is simply no teaching of coenzyme Q-10 solubilized in limonene “to form a solution” as required in claims 14 and 22.

2. The presently claimed ranges are not the result of “routine optimization” because the cited art does not recognize that coenzyme Q10 may be solublized in limonene “to form a solution.”

According to the M.P.E.P., even where disclosed ranges do not overlap, it may be obvious to optimize conditions, including a concentration range. M.P.E.P. § 2144.05(II). For example, “[w]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation,” because it is “[t]he normal desire of scientists or artisans to improve upon what is already generally known.” *Id.* citing to *In re Aller*, 220, F.2d 454 (CCPA 1955) and *In re Peterson*, 315 F.3d at 1330.

Before optimization may be found to be obvious, the M.P.E.P. requires that the optimized “parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *Id.* citing *In re Antonie*, 559 F.2d 618 (CCPA 1977).

In its rejection of claims reciting percentages of coenzyme Q10 in limonene, the Office concedes that “Garti et al. do not disclose the solubility limit of CoQ10 in d-limonene,” but argued that “it would have been obvious to one of ordinary skill in the art at the time of the invention to dissolve as much co Q10 as possible in the d-limonene and in the solvent mixture of limonene.” In supporting this argument the Office contends that “[t]he solubility limit of CoQ10 in any solvent or solvent mixture would have been readily determined by the artisan of ordinary skill, such a determination being routine in the art.” *Id.*

Simply put, the solubility limit of CoQ10 would not have been readily determined by the reasonably skilled artisan, because the cited art taught that solubility limit of coenzyme Q10 in any oil is many fold lower than 2.45%. As described above, Garti teaches that a multi-component emulsions must be used to obtain even a 2.45% coenzyme Q10 composition. Thus, according to Garti, it certainly is not within the realm of “routine optimization” to arrive at a percent concentration that is nearly an order of magnitude higher than the maximum taught by Garti.

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. Again, while Elstner claims a preparation “contain[ing] a terpinene-containing etherial oil or terpinene,” and coenzyme Q (Q10), there is simply no teaching of coenzyme Q-10 solubilized in limonene “to form a solution” as required in claims 14 and 22.

3. The cited art teaches away from using solutions of coenzyme Q-10 in limonene to form a solution, “wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight,” as currently claimed.

According to the M.P.E.P. “[a] prima facie case of obviousness may . . . be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.” § 2144.05(III).

The cited art discloses that coenzyme Q10 is generally insoluble in oils and that the maximal solubility in a single compound is many fold lower than the presently claimed range. Garti teaches that even minimal solubility of coenzyme Q10 (2.45%) requires the use of a multi-component emulsion, which traps the insoluble coenzyme Q10. Specifically, Garti is directed to delivery methods for “[l]ipophilic compounds [that] are non-soluble in aqueous systems and frequently also in food grade organic solvents such as vegetable oils or alcohols.” Garti, para. [0030]. Garti identifies coenzyme Q10 as one such lipophilic nutraceutical. *Id.* Garti solves the insolubility problem by avoiding the use of a single solubilizing compound. Even so, Garti’s most concentrated coenzyme Q10 emulsion is only 2.45%. Example C:1 Micellar concentrate, para. [0040].

Garti is explicit in requiring the use of a multi-component emulsion to achieve the 2.45% coenzyme Q10 composition. More importantly, Garti teaches that the 2.45% coenzyme Q10 composition is far better than what can be expected with limonene, or any oil, alone. Garti states that “[t]he capability of . . . nano-sized self-assembled structured concentrates to solubilize the desired active component exceeds many-fold the solubility capacities of the aqueous or oil phase alone or of the aqueous or oil phase in the presence of an appropriate surfactant.” Garti, para. [0029]. Thus, Garti materially and explicitly teaches away from a solution of coenzyme Q10 and limonene “wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight.”

EP0888774, RITO, and Elstner can not compensate for the failings of Garti. Neither Soft Gel, nor RITO teach or even mention limonene. While Elstner claims a preparation “contain[ing] a terpinene-containing etherial oil or terpinene,” and coenzyme Q (Q10), there is simply no teaching of conenzyme Q-10 solubilized in limonene “to form a solution” as required in claims 14 and 22.

4. Because independent claims 14 and 22 are non-obvious in light of the cited art, all claims depending therefrom are also non-obvious.

The M.P.E.P. states that “[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.” § 2143.03 *citing, In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

As detailed above, claims directed to a solution of coenzyme Q10 in limonene, “wherein said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight” are not obvious in light of the cited art. Thus, because claims 14 and 22 are non-obvious, all other claims that depend from these independent claims are also non-obvious.

CONCLUSION

After entry of the above listing of claims and remarks, 14-15, 18-20, 22-23, 32-34, 36-43, and 45-55 are pending in the application. In accordance with the amendments and arguments set forth herein, the Applicant respectfully submits the application and all claims are in a condition for allowance, and requests such prompt allowance.


This Amendment and Response is filed with a Request for Continued Examination (RCE) and a petition for a five-month extension of time, and a request to charge Deposit Account No. 04-1415 for the RCE fee in the amount of \$405 and the extension of time fee in the amount of \$1,175. The Applicant believes no further fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this as authorization therefor and please charge such fees to Deposit Account number 04-1415.

Should any issues remain that the Examiner believes may be dealt with in a telephone conference, he is invited to contact the undersigned at 303-629-3400.

Dated this 18th day of December, 2010.

17 (TAW)

Respectfully submitted,



Timothy A. Worrall, Ph.D., Registration No. 54,552
USPTO Customer No. 20686

DORSEY & WHITNEY LLP
370 17th Street, Suite 4700
Denver, Colorado 80202-5647
Telephone: 303-629-3400
Facsimile: 303-629-3450